Proposed Decision Memo for Carotid Artery Stenting in Post-Approval Studies (CAG-00259N)

Decision Summary

The Centers for Medicare and Medicaid Services (CMS) has determined that the evidence is adequate to conclude that percutaneous transluminal angioplasty (PTA) with carotid stent placement is reasonable and necessary when performed consistent with Food and Drug Administration (FDA) approval of the carotid stent device and in a FDA required post-approval study.

Coverage of FDA-required post approval studies is limited to this technology only. CMS may choose to address general coverage of FDA-required post approval studies in a future coverage determination.

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Proposed Decision Memo

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SUBJECT: Coverage Decision Memorandum for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting.

DATE: September 1, 2004

Decision

The Centers for Medicare and Medicaid Services (CMS) has determined that the evidence is adequate to conclude that percutaneous transluminal angioplasty (PTA) with carotid stent placement is reasonable and necessary when performed consistent with Food and Drug Administration (FDA) approval of the carotid stent device and in a FDA required post-approval study.[1]

Coverage of FDA-required post approval studies is limited to this technology only. CMS may choose to address general coverage of FDA-required post approval studies in a future coverage determination.

Background

Obstructive lesions in the carotid arteries have the potential to cause substantial morbidity, mortality and long-term disability for Medicare patients. In the United States, about 700,000 people have a new or recurrent stroke each year.[2] Cerebral infarctions account for about "80% to 85% of all strokes."[3] Of all cerebral infarctions, about "20% to 30% are due to atherothrombosis or thromboembolism from the extracranial or intracranial vessels"[4] including the carotid arteries. Carotid endarterectomy, a surgical procedure that involves removal of significant obstructive plaque from one or more carotid artery, has been used to treat symptomatic carotid artery stenosis. In recent years, percutaneous transluminal angioplasty (PTA) of the carotid artery with stent placement was developed and has been studied for symptomatic carotid artery stenosis. CMS recognized that making available new, effective therapies aimed at addressing treatment and prevention of cerebrovascular disease was important to Medicare beneficiaries and provided limited coverage for carotid angioplasty-stenting in FDA Category B Investigational Device Exemption (IDE) studies.

With new FDA device approval, coverage under the IDE trial policy is no longer available and would not be applicable to FDA-required post approval studies. Thus, this memorandum addresses specifically Medicare coverage of FDA-required post approval studies for PTA of the carotid artery with stent placement, and briefly FDA-required post approval studies in general.

History of Medicare Coverage

On July 1, 2001 CMS posted a NCD announcing the modification of CIM 50-32 Percutaneous Transluminal Angioplasty[5] to allow coverage of PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with FDA approved protocols governing Category B IDE clinical trials. The NCD further stated that performance of PTA in the carotid artery when used outside of approved protocols governing Category B IDE clinical trials remained a noncovered service.

Since the issuance of our original NCD, endovascular interventions including carotid stenting systems have been improved and refined and a number of studies and trials have concluded. We currently have an open National Coverage Determination (CAG-00085R)[6] and are completing our detailed review of the evidence to determine whether PTA of the carotid artery concurrent with carotid stent placement may be reasonable and necessary for Medicare beneficiaries outside of IDE trials and FDA mandated post-approval studies; our determination will be issued in the next several months.

FDA Status

FDA has approved the premarket application (PMA) for one company's carotid stent system with a requirement to conduct a post-approval study. The approval was for the carotid stent used in conjunction with a compatible embolic protection system for the treatment of patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet 2 additional criteria:

- Patients with neurological symptoms and $\geq$50% stenosis of the common or internal carotid artery by ultrasound or angiogram OR patients without neurological symptoms and $\geq$80% stenosis of the common or internal carotid artery by ultrasound or angiogram, AND
- Patients must have a reference vessel diameter within the range of 3.6 mm and 9.1 mm at the target lesion.

FDA has agreed with the sponsor's proposal to conduct a multicenter post-approval study in the practices of physicians at both academic and private hospitals, who will have a mixture of high, medium and low annual carotid stent implant volumes. The post-approval study will gather data on patient outcomes including stroke and rare adverse events.

In addition, the FDA is considering a PMA for another company's carotid stent system, which was favorably reviewed by its circulatory system device panel, with a recommendation for approval with certain conditions. The FDA panel also favorably viewed the firm's proposal for a post-approval carotid stent study "for a 1000 patient/100 center study conducted by physicians at both academic and private hospitals, who will have a mixture of high, medium and low annual carotid stent implant volumes, geographically distributed."

CMS Analysis

FDA approval provides reasonable assurance of the safety and effectiveness of a medical device in general, but does not show that use of the device is reasonable and necessary in any particular circumstance. In National Coverage Determinations, CMS reviews available evidence to determine if or when the use of a particular item or service is "reasonable or necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member," which is the standard for Medicare coverage set out in section 1862(a)(1)(A) of the Social Security Act.

CMS has approved coverage of items or services in clinical trials that contain patient safeguards and protections that reasonably assure patient safety and ongoing monitoring of patients to maximize health outcomes. These clinical trials are designed to evaluate the safety and effectiveness of medical care, and are crucial to potentially improving clinical practice. For a given device, a FDA-required post-approval study may include most, if not all, of the patient safeguards and protections that are present in a clinical trial reviewed by FDA for an IDE application. The protocols for such studies are reviewed and approved by Institutional Review Boards (IRBs) for the protection of human subjects. An IRB is a committee designated by an institution to review and approve research involving human subjects, and to protect the rights, safety and welfare of the human subjects. IRBs are formed in accordance with regulations and are registered with the U.S. Department of Health and Human Services.[7]

In general, CMS believes that FDA-required post approval studies can ensure patient protection while developing information on appropriate device use and best practices that can be made available to providers and practitioners. These patient protections and safeguards would only be available to the extent that post approval study data can be made available in some form to providers and practitioners to inform their decisions, monitor performance quality, and identify best practices. We do not set forth precise standards for data sharing practices, which we leave open to those conducting the study. But we do require that the collection and distribution of health information be consistent with the *Standards for Privacy of Individually Identifiable Health Information*.[8]

Post approval studies can also provide data on the generalizability of the results of an IDE clinical trial to other populations, settings and treatment regimens. In addition, these post-approval studies will serve to gather long-term safety and effectiveness data on the device for the approved indication. Often, IDE trials have only limited follow up times, and do not provide adequate long-term data. Post-approval studies thus are important in demonstrating that new technologies have acceptable long-term benefits and safety profiles. Post-approval studies can also identify follow-up patient care needs. The data and results can provide a basis for ongoing quality assurance and for providers and practitioners to identify necessary skills to achieve outcomes equal to or better than those seen in the IDE trial. Ensuring that post approval studies continue to be conducted and completed increases the level of evidence available so that coverage policies can be refined and adjusted based on high quality evidence.

CMS recognizes the importance of carotid artery stenosis as a risk factor for stroke and the importance of making available new FDA approved technologies to Medicare beneficiaries. CMS believes that coverage of FDA required post approval trials on PTA of the carotid artery concurrent with carotid stent placement would be appropriate for the following reasons: (1) there is a significant disease burden from stroke and carotid artery stenosis in the Medicare population; (2) there is a promising new treatment for carotid artery stenosis that also has considerable patient risks; (3) coverage can no longer be provided under the IDE clinical trials policy since the device has been approved by the FDA; and (4) the collected data may provide an opportunity for practitioners to determine which patients are most appropriate for carotid artery stenting and to reinforce IDE trial data on health outcomes and adverse events.

Therefore, CMS concludes that PTA of the carotid artery concurrent with carotid stent placement is reasonable and necessary when performed consistent with FDA approval of the carotid stent device and in an FDA-required post-approval study.

Conclusion

CMS has determined that percutaneous transluminal angioplasty (PTA) with carotid stent placement is reasonable and necessary when performed consistent with Food and Drug Administration (FDA) approval of the carotid stent device and in a FDA required post-approval study.

Coverage of FDA-required post approval studies is limited to this technology only. CMS may choose to address general coverage of FDA-required post approval studies in a future coverage determination.

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1. Guidelines governing post approval studies are outlined in 21 CFR 814.82 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=814.82.
2. American Heart Association. Heart Disease and Stroke Statistics - 2004 Update.
3. Topol EJ (editor). Textbook of Cardiovascular Medicine, 2002. ISBN 0-7817-3225-5.
4. Ibid.
5. CIM 50-32 coincides with updated NCD Manual Section 20.7
6.CAG00085R
7. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.103
8. Privacy Rule - Health Insurance Portability and Accountability Act of 1996.

(http://www.os.dhhs.gov/ocr/privacysummary.pdf)

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